COMMONWEALTH of VIRGINIA
Department of Health
KAREN REMLEY, MD, MBA, FAAP
STATE HEALTH COMMISSIONER
P O BOX 2448
RICHMOND, VA 23218
TTY 7-1-1 OR
1-800-828-1120

UPDATE: FUNGAL MENINGITIS ASSOCIATED WITH POTENTIALLY CONTAMINATED PRODUCT

October 12, 2012

Dear Clinician,

This letter is being sent to physicians in southwestern Virginia to update you on the outbreak of fungal meningitis among patients who received epidural spinal injections (ESI) containing potentially contaminated preservative-free methylprednisolone acetate from three lots prepared by the New England Compounding Center (NECC). Virginia Department of Health (VDH) is working closely with the only two medical facilities known to have received and used this product from NECC: Insight Imaging in Roanoke and New River Valley Surgery Center in Christiansburg.

This week, VDH has begun to re-contact all exposed persons who are not already under the care of an infectious disease physician. VDH will contact these individuals periodically over the next several weeks and may be contacting their primary care physicians for more information.

As of October 12, 2012, VDH is reporting 33 cases of suspected or confirmed fungal meningitis, including one (1) death. Thirty (30) cases are residents of Virginia; three (3) cases are residents of West Virginia who received an ESI at one of the Virginia facilities. Other cases are under investigation and Virginia's numbers will increase.

A preliminary descriptive analysis of the 33 case-patients found:

- 51% are male. Median age is 64 years (range 30 – 85).
- All 33 have been hospitalized.
- Symptom onset dates range from 7/31/2012 – 10/11/2012. Symptoms included: headache, 91%; neck stiffness, 58%; fever, 48%; nausea, 30%; chills 24%; back pain, 21%; photophobia, 21%; vomiting, 12%; diarrhea, 3%.
- CSF findings reveal: median WBCs 1,869 per mm^3 (range 13 – 7,454); protein 109 mg/dL (range 30 – 209); and glucose 43 mg/dL (range 7 – 120).
- Incubation period (date of last injection to symptom onset date) was a median 19 days (range 4 – 50 days).
- By procedure, 30 (91%) received lumbar ESIs; 3 (9%) received cervical/thoracic ESIs.
- 32 patients received methylprednisolone acetate from NECC lot number 06292012: one (1) patient also received an injection from lot 08102012; four (4) patients also received injections from lot 05212012.
- One (1) patient only received methylprednisolone acetate from NECC lot 05212012. While this patient meets the case definition, lymphocytes predominate in the CSF and testing for viral pathogens is ongoing.
- *Exserohilum rostratum* has been isolated in a sample from the one confirmed death. *Exserohilum* also has been detected by PCR in the CSF of several other Virginia cases.

The first date on which any of the implicated methylprednisolone lots was administered to any patient in Virginia was June 28, 2012. Virginia's data, to date, indicates the risk of infection is most strongly associated with receiving at least one ESI with NECC lot number 06292012. In Virginia, NECC lot numbers 06292012 and 08102012 were used on or after August 8, 2012. Product from these two lots was last used September 26, 2012.

Because of the unknown incubation period, illness may still develop in persons who only received NECC lot number 08102012.

Symptoms AND CSF pleocytosis (regardless of CSF protein and glucose values) AND history of having an ESI with one of the three lots of methylprednisolone in the recall issued September 25, 2012 are the key criteria for a case and are an indication for initiating empiric antifungal therapy. Consultation with an infectious disease specialist is strongly recommended for the management of these patients.

We are asking you to have a low threshold for performing an LP on symptomatic patients who had an ESI with <u>any one of the three lots</u> of methylprednisolone. Some patients' symptoms have been mild in nature. Some patients may present with neurologic symptoms, including symptoms of stroke.

In Virginia, approximately 50 patients received an injection of the recalled product into a peripheral joint. Evaluation of any patient with a suspected septic arthritis should include sending synovial fluid for fungal smear and culture. To date, there has been no report of a suspected fungal joint infection in any Virginia patient.

The VDH homepage (http://www.vdh.virginia.gov/) has links to CDC's Meningitis Outbreak webpage, which will have the most current guidelines on diagnostic testing and treatment. Please check the guidelines frequently since these recommendations change as more is learned about this infection.

We hope this information is helpful as you communicate with patients about their symptoms, their risk of infection and as you make clinical decisions regarding diagnostic testing, hospitalization, treatment, and follow-up. Please contact your local health department to report suspected cases or if you need additional information.

Sincerely,

David H. Trump, MD, MPH, MPA
State Epidemiologist & Director, Office of Epidemiology